K063076

SECTION 5: 510(k) SUMMARY

MAR 29 2007

Submitter:
Ascent Healthcare Solutions
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Phoenix, Arizona 85044

Contact:
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Date of preparation: September 28, 2006

Name of device: *Trade/Proprietary Name:* Reprocessed Diagnostic Ultrasound Catheter
Classification Name: Diagnostic Intravascular Catheter

Predicate Device	510(k) Title	Manufacturer
K992631	AcuNav™ Diagnostic Ultrasound Catheter	Acuson Corp.

Device description: Diagnostic Ultrasound Catheters are specially designed ultrasonic catheters that provide two-dimensional imaging using an ultrasound transducer. The ultrasound transducer is at the distal tip of the catheter and can be positioned for ultrasound imaging by a steering mechanism that rotates the catheter tip and variable deflection. Diagnostic Ultrasound Catheters incorporate a handpiece, a flexible shaft and a distal tip section containing an ultrasound transducer. The Ultrasound Catheter is 10 French with 90 cm insertion length.

Indications for Use: Reprocessed Diagnostic Ultrasound Catheters are intended for intravascular or intracardiac ultrasound imaging in order to provide visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart. The device is intended for use in the right heart only.

Technological characteristics: The design, materials, and intended use of Reprocessed Diagnostic Ultrasound Catheters are identical to the predicate devices. The mechanism of action of Reprocessed Diagnostic Ultrasound Catheters is identical to the predicate devices in that the same standard mechanical design, materials, and size are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions's reprocessing of Ultrasound Catheters includes removal of adherent visible soil and decontamination. Each individual Ultrasound Catheter is tested for appropriate

function of its components prior to packaging and labeling operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Diagnostic Ultrasound Catheters. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Ultrasound Catheters perform as originally intended.

Conclusion: Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Ultrasound Catheters) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2007

Ascent Healthcare Solutions
c/o Ms. Katie Bray
Regulatory Affairs Engineer
10232 South 51st Street
Phoenix, Arizona 85044

Re: K063076
Trade Name: Reprocessed Diagnostic Ultrasound Catheter (See Enclosed Model)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: NLI
Dated: March 2, 2007
Received: March 5, 2007

Dear Ms. Bray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K063076

Device Name: Reprocessed AcuNav Ultrasound Catheter

Indications For Use: Reprocessed Diagnostic Ultrasound Catheters are indicated for visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart, as well as measurement of blood flow. The Reprocessed Diagnostic Ultrasound Catheter is intended for use in the right side of the heart only.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Chumbra

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063076